



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

C. Farlow

AUG 29 1991

MEMORANDUM:

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: KS-910001; Section 24(c). Chlorothalonil (Bravo 720, EPA Reg. No. 50534-188) on dry beans. No MRID No. DEB No. 8436. DP Barcode No. D167864.

FROM: John Abbotts, Chemist *John Abbotts*
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THRU: Francis B. Suhre, Section Head *Francis B. Suhre*
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TO: Clarence Lewis, PM-22 Team
Fungicide-Herbicide Branch
Registration Division [H7505C]

The State of Kansas has approved a Section 24(c) registration for the use of the fungicide Bravo® 720 (chlorothalonil) to control rust, anthracnose, downy mildew, and cercospora leaf spot (blackeye only) on dry beans, with a 14 day PHI. State approval was granted March 25, 1991.

Note to PM: HED received this review request on 8/21/91.

Tolerances have been established for the combined residues of chlorothalonil (2,4,5,6-tetrachloroisophthalonitrile) and its 4-hydroxy metabolite (4-hydroxy-2,5,6-trichloroisophthalonitrile) on numerous commodities, including 0.1 ppm in or on dry beans (40 CFR 180.275). Chlorothalonil is a List A chemical. A Registration Standard (Guidance Document) was issued in September 1984; a Final Registration Standard and Tolerance Reassessment (FRSTR), Residue Chemistry Chapter, was issued in February 1988.

Bravo 720 contains 54% chlorothalonil (0.75 lb ai/pint).

Present CB policy is to assume that HCB residues are 0.5% of chlorothalonil residues on all crops, in the absence of residue data to the contrary (Chlorothalonil Subject File, D.F. Edwards, 8/23/88).



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Manufacturing Process Information is not Included

Proposed Use

The proposed use calls for an initial treatment during early bloom stage using 1-3/8 to 2 pints of Bravo 720 (1.03 to 1.5 lb ai) per acre per application, treatment may be repeated at 7 to 10 day intervals. Use would be restricted to beans harvested with the pods removed. Do not apply within 14 days before harvest. Do not allow livestock to graze in treated areas or feed treated plant parts to livestock.

The currently registered use for chlorothalonil on dry beans (harvested dry with pods removed) allows for 2 pints of Bravo 720 (1.5 lb ai) per acre per application. Applications can begin during early bloom stage and repeat at 7 to 10 day intervals. Do not apply within 42 days of harvest. Do not graze treated areas or feed treated plant parts to livestock.

In summary, the State of Kansas has approved reducing the PHI to 14 days from the currently authorized 42 day PHI for chlorothalonil in or on dry beans.

Chronology

On several occasions, CB (or RCB or DEB) has recommended against a 14 day PHI for chlorothalonil on dry beans, most recently with regard to Section 24(c) registrations in Nebraska (Chlorothalonil Section 24(c) File, D. McNeilly, 10/23/90, DEB No. 7086, and 2/26/91, DEB No. 7578; and J. Abbotts, 5/22/91, DEB No. 7931), because residue data indicated that the existing tolerance may be exceeded as a result of the proposed use. A summary of CB reviews on this proposed reduction in the PHI is provided here:

RCB expressed concern with a 14 day PHI over data submitted with PP 8E2065 where residues on dry beans exceeded 0.1 ppm. From these residue data, RCB recommended a tolerance of 0.1 ppm provided the petitioner limit the use to 3 applications of 1.5 lb ai per acre per application and increase the PHI from the originally proposed 14 days to 6 weeks (PP8E2065, P.V. Errico, 5/15/81).

In 1984, SDS Biotech Corporation requested a Section 24(c) registration which would reduce the PHI to 14 days when using chlorothalonil on dry beans in the state of North Dakota. In reviewing this request, RCB noted the previous residue data submitted with PP 8E2065, and concluded that the 0.1 ppm tolerance on dry beans would be exceeded as a result of unlimited applications of chlorothalonil and reducing the PHI to 14 days. RCB recommended against the 24(c) registration (PP 8E2065, L.S. Propst, 7/9/84 and 12/18/84).

In 1990, the Nebraska Department of Agriculture issued a Section 24(c) registration for the use of chlorothalonil in or on dry beans, under which the PHI was reduced to 14 days. No residue data were submitted with this Section 24(c), and DEB referred to the residue data previously submitted under PP 8E6065. DEB concluded that the data available did not support decreasing the PHI to 14 days, and recommended against the 24(c) registration; DEB noted it would reconsider the recommendation upon receipt of adequate residue data to support the proposed use (NE-900004, D. McNeilly, 10/23/90, DEB No. 7086).

The state of Nebraska subsequently submitted residue data from two different sets of field trials to support the Section 24(c) registration. The results of the first set of trials, conducted in IL, MN, and ND, are reproduced below as reported (NE-900004, D. McNeilly, 2/26/91, DEB No. 7578).

Table 1. Combined Residues of Chlorothalonil and its 4-Hydroxy Metabolite in or on Dry Beans (pods removed), First Set of Trials.

Table No.	PHI, days	Number of applications	Pints applied/ application	Residue range, ppm
5	43	2	2 (0.7X)	ND-0.08
6	43	2	3 (1.04X)	ND-0.09
6	43	2	4 (1.4X)	ND-0.19
7	40	3	2 (0.7X)	ND-0.08
8	40	3	4 (1.4X)	ND-0.08
9	28	3	4 (1.4X)	ND
10	27	1	3 (1.04X)	ND

Table note: Table No. refers to the original table in Diamond Shamrock Corp. report 463-3CR-81-0154-001.

Numbers in parentheses under the pints applied column in Table 1 indicate that some field trials applied Bravo-500, which contains a lower proportion of ai per pint (0.7X) than Bravo-720 (1.04X), the formulation for which the Section 24(c) registration was requested. 3 pints of Bravo 500 yield approximately the same amount of ai as 2 pints of Bravo 720. In reviewing these data, CB noted that there are four instances where the residue approaches the tolerance level, and one where it exceeds it. These data are for PHIs longer than 14 days, and CBRS concluded from these data that the residue with unlimited applications and a PHI of 14 days was very likely to exceed the 0.1 ppm tolerance

3

DEB 8436, Chlorothalonil Section 24, p. 4 of 7

for chlorothalonil and its 4-hydroxy metabolite in or on dry beans (NE-900004, D. McNeilly, 2/26/91, DEB No. 7578).

The state of Nebraska at the same time submitted data from a second set of field trials, conducted in CO, DE, MI, NE, ND, and TN. The results from these field trials are reproduced below as reported (D. McNeilly, 2/26/91, Ibid.):

Table 2. Combined Residues of Chlorothalonil and its 4-Hydroxy Metabolite in or on Dry Beans (pods removed), Second Set of Trials.

Table No.	PHI, days	Number of applications	Pints applied/ application	Residue range, ppm
5	14	3	2 (0.7X)	ND-0.03
5	14	3	3 (1.04X)	ND-0.03
6	0	5	3 (1.04X)	ND-0.07
6	8	4	3 (1.04X)	ND-0.03
7	13	4	3 (1.04X)	ND
9	7	5	3 (1.04X)	ND-0.04
9	14	4	3 (1.04X)	ND-0.01
10	9	4	3 (1.04X)	ND-0.03

Table note: Table number refers to the original Table number in Diamond Shamrock Corp. report 612-3CR-82-0181-001.

In reviewing these data, CBRS noted that they suggest that the tolerance would not be exceeded. However, review of the data submitted indicated that each data point consists of one sample and its duplicate. The previous set of data (Table 1), which represented longer PHIs, contained significantly more data points. The data in the first report indicate that the tolerance may be exceeded. In addition, CBRS referred to the previous field trial data which indicated that a 0.1 ppm tolerance would not be adequate to cover all residues resulting from a PHI of 14 days (PP 8E2065, P.V. Errico, 5/15/81). CBRS did not consider the limited residue data submitted in Table 2 to be sufficient to support lowering the PHI from 42 to 14 days. The data submitted did not change the concern that the tolerance may be exceeded as a result of the proposed use, which allowed an unlimited number of applications, and CBRS therefore continued to recommend against this 24(c) registration. CBRS indicated that it would reconsider this recommendation upon receipt of residue data clarifying the discrepancies between the two data sets (dry

4

DEB 8436, Chlorothalonil Section 24, p. 5 of 7

beans) indicated in Tables 1 and 2. (D. McNeilly, 2/26/91, DEB No. 7578)

In response to the CB review of 2/26/91, the State of Nebraska submitted a report on residue data, "Determination of residues of chlorothalonil (SDS-2787), SDS-3701, SDS-46851, HCB, and PCBN in Crops: Dry Beans." (MRID No. 418441-01 for the report, -00 for the transmittal letter). Field trials were conducted at four locations in CO, MI, ND, and NE. Residue data from these trials are summarized in the table below:

Table 3. Residues of Chlorothalonil (SDS-2787) and its 4-Hydroxy Metabolite (SDS-3701) in or on Dry Beans (pods removed).

Location	Applica- tions	Bravo Product, ai/A	PHI, days	Residue range, ppm	
				SDS-2787	SDS-3701
ND	8	720, 1.5 lb	14	ND	ND
NE	3	720, 1.5 lb	14	ND	ND-0.016
MI	4	720, 1.5 lb	14	ND	ND
CO	2	720, 1.5 lb	18	ND	0.012
CO	2	C/M, 1.08 lb	18	ND	ND

Table notes: ND is <0.01 ppm for SDS-2787 and SDS-3701.

In addition to the samples above, data were also provided for residues of hexachlorobenzene; HCB residues for all samples were below the limits of detection, <0.003 ppm. Bravo C/M is a formulation of chlorothalonil in combination with copper and maneb.

These data suggest that tolerances would not be exceeded. However, except for the field trials in ND, trials were limited to 2-4 applications, conditions which did not address the concern that applications would be unlimited under the Section 24(c) proposed use. Moreover, each data set represents duplicate laboratory determinations of single samples. This is the same type of data as that represented in Table 2, and does not explain why earlier residues were so high. The earlier review desired data clarifying the discrepancies between the residue samples of Tables 1 and 2 (D. McNeilly, 2/26/91). The cover letter from the state of Nebraska contained a conclusory statement that the most recent set of residue data "will clarify any questions regarding

potential residue problems" (MRID 418441-00). However, neither the submitted report nor the cover letter provided information that resolved the discrepancies between the data in Table 2 with those in Table 1 nor residue data submitted with PP 8E2065.

CBRS concluded that this latest data submission from the State of Nebraska was also not sufficient to support reducing the PHI from 42 to 14 days. CBRS recommended against the Nebraska Section 24(c) registration; CBRS was willing to reconsider this recommendation upon receipt of residue data clarifying the discrepancies between the data sets discussed in Tables 1, 2, and 3 (Chlorothalonil Section 24(c) file, J. Abbotts, 5/22/91, DEB No. 7931).

Present Submission

The present submission from the State of Kansas contained no residue data. The discrepancies which caused an earlier recommendation against the State of Nebraska Section 24(c) request have not been resolved, and CBRS must therefore recommend disapproval of the Kansas Section 24(c) registration, as well.

Conclusions

Since 1981, CB has on several occasions recommended against reducing the PHI for chlorothalonil on dry beans from 42 to 14 days. There is no prohibition on changing this position, but the concerns previously expressed will have to be adequately resolved. Two major issues have been of concern:

--That residue data previously submitted indicate that the tolerance of 0.1 ppm for chlorothalonil and its 4-hydroxy metabolite in or on dry beans may be exceeded if the PHI is reduced from 42 to 14 days.

--That unlimited applications would be allowed under the proposed use that would reduce the PHI.

With regard to the second concern, a representative of SDS Biotech Corporation in 1984 wrote:

"[S]ince it would not be economically feasible for a grower to make more than three applications of BRAVO on dry beans, we would not oppose going back to these states and adding this restriction to alleviate the Agency's concern." (Chlorothalonil Section 24(c) file, R.P. Burton, SDS Biotech Corporation, letter to H.M. Jacoby, Fungicide-Herbicide Branch, U.S. EPA, July 13, 1984.)

Limiting the number of applications to 3 would be a first step in addressing the concerns of CBRS. Nonetheless, petitioners would still have to submit detailed residue data to indicate that tolerances would not be exceeded under the proposed use, and

6

DEB 8436, Chlorothalonil Section 24, p. 7 of 7

would have to resolve discrepancies with previously submitted residue data. Submitting duplicate laboratory determinations of a single sample from a field test is not sufficient to meet these concerns.

Residue data for the Nebraska Section 24(c) registration were generated by Hazleton Laboratories; no data were generated by Craven Laboratories.

Recommendation

Since 1981, CB and its predecessor branches have taken the position that the 0.1 ppm tolerance for chlorothalonil and its 4-hydroxy metabolite in or on dry beans may be exceeded as a result of unlimited treatments and a PHI of 14 days. The submission from the State of Kansas contains no residue data, and does not change the concern that the tolerance may be exceeded as a result of the proposed use.

Therefore, CBRS recommends disapproval of this 24(c) registration. CBRS is willing to reconsider this recommendation upon receipt of residue data from KS clarifying the discrepancies between the data sets discussed in this review in Tables 1, 2, and 3.

We further recommend that a copy of this review be furnished to Mr. Gary E. Boutz, Pesticide Law Administrator, Plant Health Division, Kansas State Board of Agriculture.

Note to PM: The letter of 6/27/90 from Fermenta ASC Corporation to the State of Kansas states that this Section 24(c) registration has been granted in CO, and is being sought in ND and NE. For the reasons outlined in the Chronology Section of this review, CB has recommended against the registrations in ND and NE. CBRS has no record of having reviewed a Section 24(c) registration in CO for the use of chlorothalonil on dry beans. If that 24(c) registration is similar to those approved by NE and KS, CBRS would recommend disapproval of the CO registration as well, on the grounds that in the absence of sufficient residue data to the contrary, the existing tolerance may be exceeded as a result of the proposed use.

cc:Circ; Abbotts; 24(c) File; RF; Chlorothalonil SF;
PIB/FOD (C.Furlow)
RDI:FBSuhre:8/28/91:EZager:8/28/91
H7509C:CBII-RS:JAbbotts:CM-2:Rm812A:557-8230:8/29/91

7